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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,175	10/29/1999	STEPHEN A. LESKO	CW-304	6875

7590

03/26/2003

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/430,175

Applicant(s)
Lesko et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 9-25, 28-41, 43-56, and 58-70 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 9-25, 28-41, 43-56, and 58-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. Claims 5, 9, 10, 53 and 54 have been amended. Claims 1, 2, 4, 5, 9-25, 28-41, 43-56 and 58-70 are under consideration.

3. The rejection of claims 1, 2, 4, 5, 9, 10, 11, 12, 33-38, 40, 41, 43-46, 51, 53-56, 59, 62-70 under 35 U.S.C. 102(a) as being anticipated by Wang et al (International Symposium on Biology of Prostate Growth, March 1998, reference AS18 of the IDS filed 2/15/2002) is maintained for reasons of record.

The Declaration under 37 CFR 1.132 filed November 8, 2002 is insufficient to overcome the rejection of Claims based upon as set forth in the last Office action because: Dr. Paul O.P. Ts'o declares that none of the co-authors of the reference by Wang et al made any inventive contribution to the invention claimed in the instant application. This has been considered but not found persuasive as of this time Wang et al is an inventor of the instant application. Furthermore, the Declaration does not give any explanation of why Steven Lesko, an instant inventor, was not a co-author of the Wang et al reference. In the event that Wang et al is no longer an instant inventor, the inventive entity will be Ts'o and Lesko. A publication attributed solely to Ts'o within a year of the filing date is a publication by a different inventive entity and the rejection under 102(a) will stand.

4. The rejection of Claims 1, 11, 12, 13, 14, 16, 17, 37, 38, 40, 41, 45, 46, 60, 62 and 70 under 35 U.S.C. 102(b) as being anticipated by Shackney et al (Cytometry, 1995, Vol. 22, pp. 282-291, reference AT8 in the IDS filed 4/27/00) is maintained for reasons of record. Applicant argues that the combination of references fails to anticipate the instant invention as Shackney et al does not teach the detection of a single circulating epithelial cell. This has been considered but

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not found persuasive. Applicant is directed to page 283, column 2, wherein it is states that "single cell suspensions were spread on slides". As Fish studies were carried out with these slide of single cells, it is again concluded that single circulating cells were indeed detected.

5. The rejection of Claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62, 70 and Claims 47, 49, 50 and 52 under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (Experimental Hematology, 1995, Vol. 23, pp. 1062-1068, reference AS9 of the IDS filed 4/27/00) in view of Waggoner et al (Ref AT15 of the IDS) and Galbraith et al (reference AS15 of the IDS) and Dale et al (Proc Annu Meet Am Soc Clin Oncol, 1995, Vol. 14, page A1308) and Frudakis et al (6,344,550) and Gross et al (PNAS, 1995, vol. 92, pp. 537-541, cited in a previous Office action) as applied to Claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62 and 70 above, and further in view of the abstract of Zhang et al (Chinese Journal of Surgery, 1997, Vol. 35, pp. 474-477) and the abstract of Kute et al (Cytometry, 1983, Vol. 4, pp. 132-140) is maintained for reasons of record.

6. The rejection of claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62, 70 and 59 under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (Experimental Hematology, 1995, Vol. 23, pp. 1062-1068, reference AS9 of the IDS filed 4/27/00) and Waggoner et al (Ref AT15 of the IDS filed 1/28/01) and Galbraith et al (reference AS15 of the IDS filed 1/28/01) and Dale et al (Proc Annu Meet Am Soc Clin Oncol, 1995, Vol. 14, page A1308) and Frudakis et al (6,344,550) and Gross et al (PNAS, 1995, vol. 92, pp. 537-541, cited in a previous Office action) as applied to claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62 and 70 above, and further in view of Ferrari et al (Proc Annu Meet Am Assoc Cancer Res, 1996, vol. 37, pp. A1686) is maintained for reasons of record.

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7. The rejection of claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62, 70, 59 and claims 47, 48 and 52 under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (Experimental Hematology, 1995, Vol. 23, pp. 1062-1068, reference AS9 of the IDS filed 4/27/00) in view of Waggoner et al (Ref AT15 of the IDS filed 1/26/01) and Galbraith et al (reference AS15 of the IDS) and Dale et al (Proc Annu Meet Am Soc Clin Oncol, 1995, Vol. 14, page A1308) and Frudakis et al (6,344,550) and Gross et al (PNAS, 1995, vol. 92, pp. 537-541, cited in a previous Office action) and Ferrari et al (Proc Annu Meet Am Assoc Cancer Res, 1996, vol. 37, pp. A1686) as applied to claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62 and 70 above, and further in view of the abstract of Takeda et al (Cancer, 1996, Vol. 77, pp. 934-940) is maintained for reasons of record.

8. The rejection of claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62, 70 and claims 53 and 55 under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (Experimental Hematology, 1995, Vol. 23, pp. 1062-1068, reference AS9 of the IDS filed 4/27/00) in view of Waggoner et al (Ref AT15 of the IDS filed 1/28/01) and Galbraith et al (reference AS15 of the IDS filed 1/28/01) and Dale et al (Proc Annu Meet Am Soc Clin Oncol, 1995, Vol. 14, page A1308) and Frudakis et al (6,344,550) and Gross et al (PNAS, 1995, vol. 92, pp. 537-541, cited in a previous Office action) in view of Thomas et al (US 6,117,985). Claims 1, 2, 4, 5, 9, 10-13, 16-25, 28-36, 40, 41, 43-46, 51, 54, 56, 58, 60, 62, 70 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (Experimental Hematology, 1995, Vol. 23, pp. 1062-1068, reference AS9 of the IDS filed 4/27/00) in view of Waggoner et al (Ref AT15 of the IDS filed 1/28/01) and Galbraith et al (reference AS15 of the IDS filed 1/28/01) and Dale et al (Proc Annu Meet Am Soc Clin Oncol, 1995, Vol. 14, page A1308) and Frudakis et al (6,344,550) and Gross et al (PNAS, 1995, vol. 92, pp. 537-541, cited in a previous Office action) in view of the abstract of Z'Graggen et al Pancreas, 1997, Vol. 15, No.4, page 463) or the abstract of Leather et al (British Journal of surgery, 1993, vol. 80, pp.

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777-780) or the abstract of Komeda et al (Cancer, 1995, vol. 75, pp. 2214-2219) is maintained for reasons of record.

9. Applicant argues that the combination of references to not anticipate the disclosed invention because the technique of flow cytometry used by Simpson et al characterizes populations of cells rather than single cells. Applicant further argues that none of the supporting references cures the deficiency of Simpson et al with regard to the characterization of single circulating epithelial cancer cells. This has been considered but not found persuasive. The instant claims are drawn to a method of characterizing single circulating epithelial cancer cells and as such is not limited to a method wherein only one cell at a time is scrutinized. If a population of single circulating epithelial cells is characterized by flow cytometry it is a method of characterizing single circulating epithelial cancer cells. Further, it is noted that the claims are drawn to "cells" in the plural and also the definition of "single cell environment" as in claim 54 is defined by the specification to mean "a single cell or a group of cells" as pointed out on page 5 of applicant's response.

10. All other rejections and objections as set forth in Paper no. 16 are withdrawn.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 24, 2003


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